

13. Instruct patients not to open the blister until ready to use FENTORA and not to store the tablet in a temporary container such as a pill box, once it has been removed from the blister package.
14. Instruct patients that FENTORA tablets are not to be swallowed whole; this will reduce the effectiveness of the medication. Tablets are to be placed between the cheek and gum above a molar tooth and allowed to dissolve. After 30 minutes if remnants of the tablet still remain, patients may swallow it with a glass of water.
15. Caution patients to talk to their doctor if breakthrough pain is not alleviated or worsens after taking FENTORA.
16. Instruct patients to use FENTORA exactly as prescribed by their doctor and not to take FENTORA more often than prescribed.
17. Caution patients that FENTORA can affect a person's ability to perform activities that require a high level of attention (such as driving or using heavy machinery). Warn patients taking FENTORA of these dangers and counsel them accordingly.
18. Warn patients to not combine FENTORA with alcohol, sleep aids, or tranquilizers except by the orders of the prescribing physician, because dangerous additive effects may occur, resulting in serious injury or death.
19. Inform female patients that if they become pregnant or plan to become pregnant during treatment with FENTORA, they should ask their doctor about the effects that FENTORA (or any medicine) may have on them and their unborn children.

20. Advise patients and caregivers that if they have been receiving treatment with FENTORA and the medicine is no longer needed they should flush any remaining product down the toilet, and if they then need further assistance, contact Cephalon, Inc., at 1-800-896-5855.

17.2 Disposal of Unopened FENTORA Blister Packages When No Longer Needed

Patients and members of their household must be advised to dispose of any unopened blister packages remaining from a prescription as soon as they are no longer needed.

To dispose of unused FENTORA, remove FENTORA tablets from blister packages and flush down the toilet. Do not flush the FENTORA blister packages or cartons down the toilet.

Detailed instructions for the proper storage, administration, disposal, and important instructions for managing an overdose of FENTORA are provided in the *FENTORA Medication Guide*. Instruct patients to read this information in its entirety and provide an opportunity to have their questions answered.

In the event that a caregiver requires additional assistance in disposing of excess unusable tablets that remain in the home after a patient has expired, instruct them to call the Cephalon toll-free number (1-800-896-5855) or seek assistance from their local DEA office.

MEDICATION GUIDE

FENTORA® (fen-tor-a) CII

(fentanyl citrate) buccal tablet

100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg

IMPORTANT:

Do not use FENTORA unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep FENTORA in a safe place away from children.

Get emergency help right away if:

- **a child takes FENTORA. FENTORA can cause an overdose and death in any child who takes it.**
- **an adult who has not been prescribed FENTORA uses it**
- **an adult who is not already taking opioids around-the-clock, uses FENTORA.**

These are medical emergencies that can cause death. If possible, try to remove FENTORA from the mouth.

Read this Medication Guide completely before you start using FENTORA, and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

What is the most important information I should know about FENTORA?

FENTORA can cause life-threatening breathing problems which can lead to death.

1. **Do not use FENTORA if you are not opioid tolerant.**
2. If you stop taking your around-the-clock opioid pain medicine for your cancer pain, **you must stop** using FENTORA. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
3. **Use FENTORA exactly as prescribed by your healthcare provider.**
 - You must not use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
 - You must wait at least 4 hours before treating a new episode of breakthrough pain with FENTORA. **See the Medication Guide section “How should I use FENTORA?” and the Patient Instructions for Use at the end of this Medication Guide for detailed information about how to use FENTORA the right way.**
4. **Do not switch from FENTORA to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of FENTORA is not the same as the amount of fentanyl in other medicines that contain

fentanyl. Your healthcare provider will prescribe a starting dose of FENTORA that may be different than other fentanyl containing medicines you may have been taking.

5. **Do not** use FENTORA for short-term pain that you would expect to go away in a few days, such as:
 - pain after surgery
 - headache or migraine
 - dental pain
6. **Never give FENTORA to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.

FENTORA is a federally controlled substance (CII) because it is a strong opioid (narcotic) pain medicine that can be misused by people who abuse prescription medicines or street drugs.

- **Prevent theft, misuse or abuse. Keep FENTORA in a safe place** to protect it from being stolen. FENTORA can be a target for people who abuse (narcotic) medicines or street drugs.
- **Selling or giving away this medicine is against the law.**

FENTORA is available only through a program called the FENTORA REMS program. To receive FENTORA, you must:

- talk to your healthcare provider
- understand the benefits and risks of FENTORA
- agree to all of the instructions
- sign the Patient-Prescriber Agreement form.

What is FENTORA?

- FENTORA is a prescription medicine that contains the medicine fentanyl.
- FENTORA is used to manage breakthrough pain in adults with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain.
- FENTORA is started only after you have been taking other opioid pain medicines and your body has become used to them (you are opioid tolerant). Do not use FENTORA if you are not opioid tolerant.
- You must stay under your healthcare provider's care while using FENTORA.
- FENTORA is only:
 - available through the FENTORA REMS program
 - given to people who are opioid tolerant

It is not known if FENTORA is safe and effective in children under 18 years of age.

Who should not use FENTORA?

Do not use FENTORA:

- **if you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines.**
- for short-term pain that you would expect to go away in a few days, such as:
 - pain after surgery
 - headaches or migraine
 - dental pain
- if you are allergic to any of the ingredients in FENTORA. See the end of this Medication Guide for a complete list of ingredients in FENTORA.

What should I tell my healthcare provider before using FENTORA?

Before using FENTORA, tell your healthcare provider if you:

- have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- have or had a head injury or brain problem
- have liver or kidney problems
- have seizures
- have a slow heart rate or other heart problems

- have low blood pressure
- have mental problems including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)
- have a past or present drinking problem (alcoholism), or a family history of drinking problems
- have a past or present drug abuse problem or addiction problem, or a family history of a drug abuse problem or addiction problem
- have any other medical conditions
- are pregnant or plan to become pregnant. FENTORA may cause serious harm to your unborn baby.
- are breastfeeding or plan to breastfeed. FENTORA passes into your breast milk. It can cause serious harm to your baby. You should not take FENTORA while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with FENTORA. Sometimes, the doses of certain medicines and FENTORA need to be changed if used together.

- **Do not take any medicine while using FENTORA until you have talked to your healthcare provider. Your healthcare provider will tell you if it is safe to take other medicines while you are using FENTORA.**
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, anti-depressant medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use FENTORA?

Before you can begin to use FENTORA:

- Your healthcare provider will explain the FENTORA REMS program to you.
- You will sign the FENTORA REMS program Patient-Prescriber Agreement form.
- FENTORA is only available at pharmacies that are part of the FENTORA REMS program. Your healthcare provider will let you know the pharmacy closest to your home where you can have your FENTORA prescription filled.

Using FENTORA:

- **Use FENTORA exactly as prescribed. Do not use FENTORA more often than prescribed.**
- Your healthcare provider will change the dose until you and your healthcare provider find the right dose for you.
- **See the detailed Patient Instructions for Use at the end of this Medication Guide for information about how to use FENTORA the right way.**
- **Do not split, suck, chew, or swallow FENTORA tablets. You will get less relief for your breakthrough cancer pain.**
- **Use FENTORA tablets whole.**
- Wait 30 minutes after using FENTORA. If there is any of the FENTORA tablet left in your mouth, you may drink a glass of water to help you swallow the left over medicine.
- You must not use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
 - Use **1** dose of FENTORA for an episode of breakthrough cancer pain.
 - If your breakthrough cancer pain does not get better 30 minutes after taking the first dose of FENTORA, you can use **only 1** more dose of FENTORA as instructed by your healthcare provider.
 - If your breakthrough pain does not get better after the second dose of FENTORA, call your healthcare provider for instructions. **Do not use another dose of FENTORA at this time.**
- Wait at least **4** hours before treating a new episode of breakthrough cancer pain with FENTORA.
 - If you only need to take 1 dose of FENTORA for an episode of breakthrough pain, you must wait 4 hours from the time of that dose to take a dose of FENTORA for a **new** episode of breakthrough pain.
 - If you need to use 2 doses of FENTORA for an episode of breakthrough pain, you must wait 4 hours after the second dose to take a dose of FENTORA for a **new** episode of breakthrough pain.
- It is important for you to keep taking your around-the-clock opioid pain medicine while using FENTORA.
- Talk to your healthcare provider if your dose of FENTORA does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of FENTORA needs to be changed.

- Talk to your healthcare provider if you have more than 4 episodes of breakthrough cancer pain per day. The dose of your around-the-clock opioid pain medicine may need to be adjusted.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away. Rinse the sink or flush the toilet to dispose of any remaining tablet pieces.
- If you use too much FENTORA or overdose, you or your caregiver should call for emergency medical help or have someone take you to the nearest hospital emergency room.

What should I avoid while using FENTORA?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how FENTORA affects you. FENTORA can make you sleepy. Ask your healthcare provider when it is okay to do these activities.
- **Do not drink alcohol while using FENTORA.** It can increase your chance of getting dangerous side effects.

What are the possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

1. **Breathing problems that can become life-threatening.** See “What is the most important information I should know about FENTORA?”

Call your healthcare provider or get emergency medical help right away if you:

- have trouble breathing
- have drowsiness with slowed breathing
- have slow, shallow breathing (little chest movement with breathing)
- feel faint, very dizzy, confused, or have unusual symptoms

These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. If you have any of these symptoms, do not take any more FENTORA until you have talked to your healthcare provider.**

2. **Decreased blood pressure.** This can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down.
3. **Physical dependence. Do not stop using FENTORA or taking any other opioid without talking to your healthcare provider.** You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
4. **A chance of abuse or addiction.** This chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental health problems.
5. **Pain, irritation, or sores at the application site (on your gum or the inside of your cheek).** Tell your healthcare provider if this is a problem for you.

The most common side effects of FENTORA are:

- nausea
- vomiting
- dizziness
- low red blood cell count
- tiredness
- swelling of the arms, hands, legs and feet
- headache

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including FENTORA and is unlikely to go away without treatment. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking FENTORA.

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FENTORA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FENTORA?

- Always keep FENTORA in a safe place away from children and from anyone for whom it has not been prescribed. Protect FENTORA from theft.
- Store FENTORA at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use. Do not freeze FENTORA.
- Keep FENTORA in the original blister unit. Do not remove FENTORA from its blister packaging for storage in a temporary container, such as a pill box.
- Keep FENTORA dry.

How should I dispose of unused FENTORA tablets when they are no longer needed?

- Dispose of any unused FENTORA tablets remaining from a prescription as soon as they are no longer needed.
 - Remove the tablets from blister packages and flush them down the toilet.
- Do not flush the FENTORA packaging (card, blister units or cartons) down the toilet.
- If you need help with disposal of FENTORA, call Cephalon, Inc., at 1-800-896-5855 or call your local Drug Enforcement Agency (DEA) office.

General information about FENTORA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use FENTORA only for the purpose for which it was prescribed. Do not give FENTORA to other people, even if they have the same symptoms you have. FENTORA can harm other people and even cause death. Sharing FENTORA is against the law.

This Medication Guide summarizes the most important information about FENTORA. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about FENTORA that is written for healthcare professionals. You can also call the FENTORA REMS program at 1-888-688-6885 or visit www.actiqandfentorarems.com.

What are the ingredients in FENTORA?

Active Ingredient: fentanyl citrate

Inactive Ingredients: mannitol, sodium starch glycolate, sodium bicarbonate, sodium carbonate, citric acid, and magnesium stearate.

Patient Instructions for Use

Before you use FENTORA, it is important that you read the Medication Guide and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use FENTORA the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use FENTORA.

When you get an episode of breakthrough cancer pain, use the dose of FENTORA prescribed by your healthcare provider as follows:

- FENTORA comes packaged as a blister card containing 4 blister units. Each blister unit contains 1 FENTORA tablet. **Do not open a blister until ready to use.**
- Separate one of the blister units from the blister card by tearing apart at the perforations. Bend the blister unit along the line where indicated. The product strength of your FENTORA tablets will be printed in the boxed area shown as

XXX mcg

(See Figure 1).

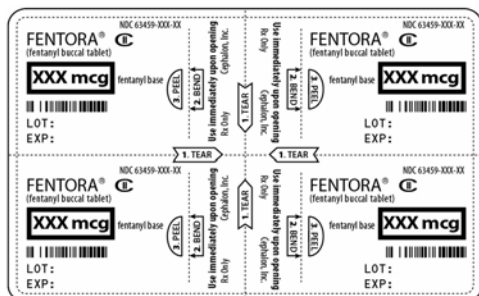


Figure 1

- Peel back foil on blister unit to expose tablet (See Figure 2).



Figure 2

- Do not push the tablet through the foil on the blister unit because this could damage the tablet.
- When removed from the blister unit, FENTORA tablet must be used right away.
- Do not split the FENTORA tablet. **Use FENTORA tablets whole.**
- Place a FENTORA tablet in your mouth above a rear molar tooth between the upper cheek and gum. **Leave the tablet in place until it dissolves.** A FENTORA tablet generally takes between 14 to 25 minutes to dissolve (See Figure 3).



Figure 3

- After 30 minutes, if there is any FENTORA left in your mouth, you may drink a glass of water to help you swallow the left over medicine.
- If you cannot use FENTORA in this manner, tell your healthcare provider. Your healthcare provider will tell you what to do. Do not split the tablet.
- **Do not split, suck, chew or swallow FENTORA tablets.** You will get less relief for your breakthrough cancer pain.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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